REMARKS/ARGUMENTS

Reconsideration is respectfully requested.

Claims 1, 6-8, 12 and 21-32 are pending and are rejected. By the present amendment, claim 22 is amended to remove any reference to cytosine arabinoside and to refer only to CODPL. Previously, claims 22-32 had been incorrectly numbered. The claims have been amended to correct the numbering to 23-33. New claim 34 has been added. No new matter has been added.

In the Office Action on page 5, the Examiner objected to the duplication of claim 22. The claims have been renumbered herein from 22-32 to 23-33. The Applicant respectfully asserts that the amendment is fully responsive to the objection and requests that the Examiner withdraw this objection as to the claims.

Claim 22 is rejected under 35 U.S.C. §112, second paragraph, for being indefinite. In response, the Applicant has amended claim 22 herein to removed the offending language "DA (daunorubincin, cytosine arabinoside)" and replaced it with "DA (daunorubincin) and CODPL". The Applicant submits that this amendment is fully responsive to the rejection and respectfully requests that the Examiner withdraw this rejection of the claim.

Claim 22 is also rejected under 35 U.S.C. §112, first paragraph, for failing to comply with the written description requirement. The Applicant submits that the amendment made to claim 22, as discussed above, is fully responsive to this rejection and respectfully requests that the Examiner withdraw this rejection of claim 22 as well.

In the office action (page 7), claim 1 is rejected under 35 U.S.C. § 103(a) as being obvious over JP 43-025506 to Yamabe et al. (IDS, June 8, 2009) in view of Okuda et al. (of record). Claims 12, 24, 25, 28 and 19 are rejected as obvious and unpatentable over Yamabe et al. in view of Okuda et al. in view of Remington's The Science an Practice of Pharmacy (PTO-892, Ref. U). Claims 21-23 and 26 are also rejected under 35 U.S.C. § 103(a) as being obvious over Yamabe et al. in view

of Okuda et al. in view of Remington's and further in view of Burzynski (U.S. 2003/0105104) in view of McCarthy et al. (of record); claim 27 over Yamabe et al. in view of Okuda et al. in view of Remington's, further in view of Chandra (U.S. 6,565,891); and claims 30-32 over Yamabe et al. in view of Okuda et al. in view of Remington's, further in view of Stuchlik et al. (PTO-892, Ref. V) as evidenced by Carrier/Fixed Oil Profiles (PTO-892, Ref. W).

The Applicant respectfully disagrees and submits that the claims are non-obvious and allowable.

The present invention provides a riboflavin derivative, 5'-lauic acid (C_{12}) ester of riboflavin. As is clear from the originally filed disclosure, the applicant has made numerous efforts and has screened out the compound of the present invention from a large amount of riboflavin derivatives including acetic acid (C_2) ester, butyric acid (C_4) esters...palmitic acid (C_{16}) esters, stearic acid (C_{18}) esters of riboflavin, and the like. Moreover, the compound of the present invention is not formulated as the conventional oral preparation of riboflavin or its derivatives, but is instead "an oil suspension preparation" which has a superior long-acting property when being administered via an intramuscular injection route. For instance, "the long-acting oil suspending preparation made from the compound of the present invention could remain effective for three months after an intramuscular injection of 150 mg" (See the last paragraph of page 3, English text). The unexpected long-acting property of the compound of the present invention and its preparation is not disclosed or suggested in any prior art, and is not obvious for those skilled in the art.

Furthermore, the applicant respectfully submits that it would not be obvious for persons skilled in the art to select the 5'-lauric acid ester of riboflavin even though Okuda et al. teaches the relative activity of tetrabutyrate, tetrapalmitate, 5'-monoburytate, and 5'-monopalmitate of riboflavin and Yamabe et al. teaches the preparation of riboflavin trilaurate. It is well known that there are four –OH groups within the chemical structure of riboflavin, and the esterification degrees (e.g., monoesters, diesters, triesters, or tetraesters), esterification sites (e.g., 5'-, 4'-, 3'-, and/or 2'-

position), and ester-forming carboxylic acids will affect substantively the properties of the resultant riboflavin derivatives, especially the bio-availability. There are a large amount of carboxylic acids between butyric acid (C_4 carboxylic acid) and palmitic acid (C_{16} carboxylic acid), which have different carbon numbers and different chain structures. Thus, it is not obvious which carboxylic acid can impart an unexpected effect to the resultant riboflavin derivative among others. In addition, the selection of esterification degrees and esterification sites is not obvious. The applicant's efforts for more than 30 years and a large amounts of inventive work, provided a selection of the specific compound of the present invention, namely, 5'-lauric acid ester of riboflavin, from numerous riboflavin derivatives. In addition, it was found that there was a superior long-acting property thereof (especially when administered via an intramuscular injection route). Respectfully, the Applicant requests that the Examiner withdraw this rejection as to claim 1 and that the comments provided above are likewise applied to new claim 34.

As for the oil suspension preparation of the present invention as in claim 6, the applicant believes that it is likewise non-obvious and allowable. The prior art does not teach any combination of 5'-lauric acid ester of riboflavin and ethyl oleate and optional camellia oil. The Applicant submits that to provide a combination of these specific ingredients, it would be overly burdensome and take a large amount of research to determine the best pharmaceutical effect from numerous pharmaceutically acceptable solvents (diluents, carriers). In particular, vegetable oils, animal oils, and oils from natural origins which are rich in oleic acid component are commonly used as diluent in the prior art, but the oleic acid component contained therein is not in a form of ethyl oleate but glycerin trioleate. Hence, the oil suspension preparation of the present invention in which ethyl oleate is used as the solvent/suspending agent/carrier/diluent is not obvious.

The applicant submits that at least for the reasons presented above, the compound, the oil suspension and the method as claimed in claims 1, 6-8, 12, and 22-34 are novel, non-obvious and allowable. The applicant respectfully requests that the Examiner withdraw this rejection as to these claims.

The applicant submits that this amendment is fully responsive to the July 1, 2009, office action. The applicant requests that the amendments be entered into the record and further requests favorable consideration.

Respectfully submitted,

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